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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/509,141

09/27/2004

Reddy Bandi Parthasaradhi

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EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

06/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/509,141 | Applicant(s) PARTHASARADHI ET AL. | |
| | Examiner Rei-tsang Shiao, Ph.D. | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 19 is/are rejected.
- 7) ☒ Claim(s) 3-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment of claims 6 and 19 in the amendment filed on March 26, 2008 is acknowledged. Claims 1-20 are pending in the application.

Responses to Amendment/Arguments

2. Applicant's arguments regarding the rejection of claims 4 and 9 under 35 U.S.C. 112, second paragraph have been fully considered and they are persuasive. The rejection of claims 4 and 9 under 35 U.S.C. 112, second paragraph has been withdrawn herein.

3. Applicant's arguments regarding the rejection of claim 19 under 35 U.S.C. 112, first paragraph filed on March 26, 2008 have been fully considered but they are not persuasive. Since applicants do not provide direct evidence that the instant pharmaceutical compositions comprising candesartan cilexetil form III are stable after the processes of preparing (i.e., i.e., mixing, grinding, and compressing, or converting into the instant form IV), the rejection of claim 19 under 35 U.S.C. 112, first paragraph is maintained. Applicants are requested to provide evidence to overcome the rejection.

4. Since claim 19 has been amended as a solid pharmaceutical composition, the rejection of claim 19 under 35 U.S.C. 102(b) over Naka et al. US 5,196,444 has been overcome in the amendment filed on March 26, 2008.

5. Applicant's arguments regarding the rejection of claims 3-11 and 19 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of Brittain's publication have been fully considered and they are persuasive. Since Naka et al. do not disclose the instant polymorph form of candesartan cilexetil 1,4-dioxane compound, therefore the rejection of claims 3-11 and 19 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of Brittain's publication has been withdrawn herein.

6. Applicant's arguments regarding the rejection of claims 1-11 and 19 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of publication of U.S. Department of Health and Human Service, Guidance for Industry, May 15, 2001, have been fully considered and they are persuasive, in part. It is noted that 1,4-dioxane is suitable and well known pharmaceutical solvent for a pharmaceutical compound (i.e., candesartan cilexetil), therefore the rejection of claims 1-2 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of publication of U.S. Department of Health and Human Service, Guidance for Industry is maintained. Cancellation of claims 1-2 would obviate the rejection.

Claim Objections

7. Claims 3-11 are objected to as being dependent claims of claim 1. Amendment of claim 3 as an independent claim, claims 3-11 would be allowable.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1626


Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D.
Primary Patent Examiner
Art Unit 1626

May 28, 2008

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| <div>Application Number</div> <div></div> | Application/Control No. | Applicant(s)/Patent under Reexamination | |
| | 10/509,141 | PARTHASARADHI ET AL. | |
| | Examiner | Art Unit | |
| | Rei-tsang Shiao, Ph.D. | 1626 | |